DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 20, 2015

Wright Medical Technology, Incorporated
Ms. Val Myles
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K142724
Trade/Device Name: BIOFOAM® Bone Wedge
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: April, 17, 2015
Received: April 20, 2015

Dear Ms. Myles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K142724

Device Name
BIOFOAM® Bone Wedge

Indications for Use *(Describe)*
The BIOFOAM® Bone Wedge is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

- Cotton and Evans Wedges:
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Opening wedge of Medial Cuneiform or Cotton osteotomies
  - Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)
  - Metatarsal/Cuneiform arthrodesis

- Midfoot Wedges
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

This device is intended for use with ancillary fixation.
The BIOFOAM® Bone Wedge is not intended for use in the spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the WMT BIOFOAM® Bone Wedge.

(a)(1). Submitted By: Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Date: September 22, 2014

Contact Person: Val Myles
Regulatory Affairs Specialist
Office - (901) 290-5162
Fax – (901) 867-4190

(a)(2). Proprietary Name: BIOFOAM® Bone Wedge

Common Name: Bone Wedge

Classification Name and Reference: 21 CFR 888.3030 – Class II

Device Product Code, Device Panel: HRS, HWC

(a)(3). Predicate Devices: K140531, K093950, K073535: BIOFOAM® Bone Wedge
K070592: Small Bone Wedge

(a)(4). Device Description

The BIOFOAM® Bone Wedge is a titanium metal foam wedge used for angular correction of small bones of the foot. It is offered with varying widths and thicknesses to accommodate a variety of small bone applications.

(a)(5). INTENDED USE

The BIOFOAM® Bone Wedge is intended to be used for internal bone fixation for bone fractures, fusions, or osteotomies in the ankle and foot, such as:

- Cotton and Evans Wedges:
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Opening wedge of Medial Cuneiform or Cotton osteotomies
  - Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy)

- Metatarsal/Cuneiform arthrodesis

- Midfoot Wedges:
  - Opening wedge osteotomies of the bones of the foot including osteotomies for Hallux Valgus
  - Nonunion of arthrodesis of the Midfoot including Metatarsal/Cuneiform arthrodesis (TMT or Lapidus)

This device is intended for use with ancillary fixation.
The BIOFOAM® Bone Wedge is not intended for use in the spine.

(a)(6). Technological Characteristics Comparison

While the subject BIOFOAM® Bone Wedge is manufactured using a modified manufacturing technique, it is technologically substantially equivalent to the predicate device. The subject and predicate devices are substantially equivalent in design, features and material.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Testing related to morphological characterization, abrasion, friction, compression and fatigue were provided to support the equivalence of the subject device and shows that no new worst-case devices are introduced in this system. Biocompatibility testing, including chemical composition and animal testing, was also completed to support the equivalence of the subject device. The safety and effectiveness of the BIOFOAM® Bone Wedge is adequately supported by testing, substantial equivalence information, materials information and comparison of design characteristics provided within this premarket notification.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate device.